

AUG 23 2005

**Atlas™ PTA Balloon Dilatation Catheter**  
**510(k) Summary of Safety and Effectiveness**  
**21 CFR 807.92.**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

**1. Submitter Information:**

Applicant: Bard Peripheral Vascular, Inc  
1625 West 3<sup>rd</sup> Street  
P.O. Box 1740  
Tempe, Arizona 85280

Phone: 480-303-2524

Fax: 480-449-2546

Contact: Genevieve Balutowski, Regulatory Affairs Specialist

**2. Subject Device Name:**

Device Trade Name: **Atlas™ PTA Balloon  
Dilatation Catheter**

Common or Usual Name: Percutaneous catheter

Classification: Class II

Classification Panel: Cardiovascular

**3. Predicate Device:**

Atlas™ PTA Balloon Dilatation Catheter (K040243, cleared 02/13/04)

**4. Summary of Change:**

The design modification to the Atlas™ PTA Balloon Dilatation Catheter as represented in this submission is additional balloon sizes. All other aspects of the subject device remain the same as the predicate device.

**5. Device Description:**

The Atlas™ PTA Balloon Dilatation Catheter is a coaxial lumen catheter with a balloon mounted on its distal tip. One lumen accommodates the insertion guidewire and the second provides a channel for inflation/deflation of the balloon. There are two radiopaque marker bands placed beneath the balloon to indicate its position within the vasculature.

**6. Intended Use of Device:**

The Atlas™ PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the iliac arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

**7. Technological Comparison to Predicate Device:**

The technological characteristics of Atlas™ PTA Balloon Dilatation Catheter are substantially equivalent to those of the predicate device, the Atlas™ PTA Balloon Dilatation Catheter, in terms of intended use, indication for use, application, user population, basic design, performance, and sterilization method.

**8. Conclusions:**

The Atlas™ PTA Balloon Dilatation Catheter met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Atlas™ PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate device, the Atlas™ PTA Balloon Dilatation Catheter.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 23 2005

Bard Peripheral Vascular, Inc.  
c/o Ms. Genevieve Balutowski  
1625 West 3<sup>rd</sup> Street  
P.O. Box 1740  
Tempe, AZ 85280-1740

Re: K052236  
Bard® Atlas™ PTA Balloon Dilatation Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: August 16, 2005  
Received: August 17, 2005

Dear Ms. Balutowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Bram D. Zuckerman*

*[Signature]* Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K052236

Device Name: Atlas™ PTA Balloon Dilatation Catheter

Indications for Use: The Atlas™ PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the iliac arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)  
DUNN R. WILSON  
Division Sign-Off  
Division of Cardiovascular Devices

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Model Number K052236

Bard Peripheral Vascular, Inc

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**BAIRD**